

SPSS by bivariate analyses with two-sided Chi-square test. In the next step the subgroups of patients with comparable treatment in clinical practice were defined and analysed in a multivariate analysis. **RESULTS:** By contrast to the recommendation of national guidelines, intensified therapy was administered less frequently in patients with the aim of "resection of metastases" (43%), whereas the highest use (64%) was reported in "patients with tumor related symptoms or at risk for rapid progression or deterioration". This group represents only 12% of the 1st line. Factors with an influence on the use of intensified therapy in daily practice were analyzed in a multivariate analysis. Three treatment clusters (comprising 89% of patient sample) were determined. (all $p < 0.05$) The cluster with significantly higher use of intensified therapy (+18% above mean value of 54%) is distinguished by: Age < 70 y., better PS ($\geq 80\%$ KI), no symptoms and/or without concomitant diseases, treatment in office based setting. Patients in this cluster show less tumor dynamics. **CONCLUSIONS:** In daily practice, the application of the decision model based on treatment aims for clinical subgroups is not generally used. Intensified treatment is more likely associated with individual patient characteristics and institutional framework. This, however, underlines the need for a critical discussion of the currently suggested decision-making models.

Cancer – Research On Methods

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THE USE OF PARAMETRIC SURVIVAL ANALYSIS TO PREDICT PROGRESSION FREE AND OVERALL SURVIVAL OF NEWLY DIAGNOSED CHRONIC MYELOID LEUKEMIA (CML) PATIENTS

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OBJECTIVES: Reimbursement agencies require estimates of the long-term (i.e. life-time) costs and benefits associated with each treatment option as part of the decision making process. As such, extrapolation of reported survival estimates is inevitable. Conventionally, information on all-cause mortality or disease progression is used. However, data for newly diagnosed CML may not be suited to such an extrapolation due to the paucity of observed events. One of solutions is to use a 'surrogate approach'. **METHODS:** A 40 year Excel® based model was created to estimate overall (OS) and progression-free (PFS) survival in newly diagnosed CML patients receiving 1st or 2nd generation tyrosine kinase inhibitor (TKI) therapy through the use of a surrogate clinical endpoint (cytogenetic response - CyR). Three response categories (complete, partial or no CyR at one year) were used. Long term response category specific OS and PFS data from IRIS clinical trial was used to inform the fitting of Weibull functions with goodness of fit assessed via the R2 statistic. CyR response rates were taken from a recently published network meta-analysis of first-line interventions. **RESULTS:** Using the conventional approach, CML patients were predicted to have an equivalent survival profile to the non-CML general population (31.6 versus 32.6 years), and the survival difference between 1st and 2nd generation drugs are 9 years (31.6 versus 22.8 years) (Botteman et al 2010). However, predicted OS estimates for 1st and 2nd generation TKI's using the surrogate approach are 18.6 and 20.1 years respectively (R2 values 0.97, 0.94). Compared to 1st generation drugs the use of 2nd generation TKI's results in approximately 1.5 additional years of survival. **CONCLUSIONS:** Extrapolating short term overall OS data in newly diagnosed CML results in inflated survival estimates. When a valid clinical surrogate is used there is a much smaller, and believable, difference in the predicted survival values.

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USE OF SURROGATE MEASURES OF SURVIVAL IN ECONOMIC EVALUATIONS OF METASTATIC BREAST CANCER TREATMENTS

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OBJECTIVES: Progression-free survival (PFS) is frequently used to establish the clinical efficacy of anti-cancer drugs. However, this surrogate measure of survival is of limited interest for the economic evaluation of these treatments. Therefore, the aim of this study is to develop a predictive model for OS based on PFS data in the context of metastatic breast cancer (mBC), which would be suitable for cost-effectiveness (cost per life-year saved) and cost-utility analyses. **METHODS:** A systematic review of the literature was conducted according to the PICO method: Population consisted of women with mBC; Interventions and Comparators were standard treatments for mBC or best supportive care; Outcomes of interest were median PFS and median OS. All selected studies were randomized trials published from 1990 to 2010. Two independent reviewers screened titles, abstracts, and full papers for eligibility. Then, reviewers independently extracted data from selected studies (median PFS, median OS, and potentially predictive covariates). The relationship between PFS and OS was assessed by calculating Pearson's correlation coefficient. Finally, statistical analyses (ANOVA and Pearson's correlation) were performed to identify covariates having a significant impact on OS. **RESULTS:** A total of 5041 studies were identified and 151 fulfilled the eligibility criteria. According to the data extracted from selected studies, there is a significant relationship between median PFS and median OS ($r = 0.373$; $p < 0.01$). Moreover, many covariates have a statistically significant impact on OS including age ($p < 0.01$), type of treatment ($p < 0.01$), line of treatment ($p < 0.01$), ECOG status ($p < 0.01$), and number and sites of metastasis ($p < 0.01$). **CONCLUSIONS:** Results of this systematic review point toward a significant relationship between PFS and OS in the context of mBC. These findings will enable the development of a predictive model for OS based on PFS and signifi-

cant covariates, which will eventually bring answers to an important challenge in the economic evaluation of anti-cancer drugs.

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ECONOMIC EVALUATION OF XELOX VS FOLFOX4 AS ADJUVANT TREATMENT FOR PATIENTS WITH STAGE III COLON CANCER IN SOUTH KOREA

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OBJECTIVES: To compare the costs of XELOX (Xeloda + Oxaliplatin) and FOLFOX4 (5-FU + Oxaliplatin + Leucovorin) for adjuvant treatment of stage III colon cancer in a South Korean setting. **METHODS:** Based on the equivalence in efficacy of XELOX from N016968 trial and FOLFOX4 from MOSAIC trial (the 5 yrs disease free survival rates were very similar 66.1% for XELOX and 66.4% for FOLFOX4), a cost-minimization approach was chosen. The model adopts a payers perspective. Efficacy/Safety data and protocol information were acquired from N016968 for XELOX, and from the MOSAIC trial for FOLFOX4. As no direct comparison of XELOX and FOLFOX4 for this indication is available, we collected several medical resource use data for these two regimens, which were chemotherapy drug doses, adverse events, hospitalization-ambulatory visits, and drug administration methods. The medical costs for FOLFOX4 were acquired from real world claims data (electronic data interchange, EDI); Catholic medical center in Korea. The direct medical costs for XELOX were also estimated by EDI from Catholic medical center with N016968 trial. Also, health care utilizations were measured. All data analyses were performed using STATA software. **RESULTS:** The total direct medical costs for XELOX were estimated to be 13,884,894 KRW and for FOLFOX4 14,509,341 KRW per patient for 24weeks of chemotherapy treatment at same body surface area. The drug costs of XELOX were 12,468,748 KRW and of FOLFOX4 10,831,699 KRW. The line costs and drug administration costs were 82,960 KRW for XELOX and, 943,176 KRW for FOLFOX4, respectively. XELOX is more expensive in terms of drug acquisition costs. However, this is more than compensated by cost savings for drug administration, ambulatory encounters, AE medications, costs for central venous lines, and hospitalization. Additional incidence of hospitalization for FOLFOX4 was 2.3 times greater than for XELOX related hospitalization. **CONCLUSIONS:** XELOX offers cost savings of 644,447 KRW (about 585 US \$) per patient compared to FOLFOX4 from the payers perspective in South Korean Universal Health Insurance System.

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BIA RESULTS COULD STOP INTRODUCTION OF COST-EFFECTIVENESS THERAPY INTO STANDARD TREATMENT : EXAMPLE FROM CROATIA

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OBJECTIVES: In order for a new therapy to be included and reimbursed on the basic list of treatments covered by Croatian Institute for Health Insurance (HZZO), it must prove to have a positive effect on the budget impact analysis (BIA). The standard therapy for patients suffering from advanced head and neck cancer is chemoradiotherapy (mainly platinum and radiotherapy). However, if chemotherapy proves to be contraindicated, only radiotherapy is applied. Cetuximab inhibits EGFR, which induces the apoptosis of cancer cells. It has been proven that the implementation of immunoradiotherapy contributes to the overall survival of patients. **METHODS:** Known costs of the standard therapy for advanced head and neck cancer were compared with the costs of the proposed new therapy (cetuximab + radiotherapy). The costs are shown in the Croatian currency (HRK) (1 Euro = 7,4 HRK). The increased costs of immunotherapy are compared to the data on efficiency from published literature. **RESULTS:** Approximately 212 patients with advanced head and neck cancer receive treatment in Croatia every year. If chemotherapy is contraindicated, a standard radiotherapy is applied (42 patients). The HZZO spends yearly 840.000,00 HRK on the treatment of those patients. The inclusion of cetuximab into the standard therapy would increase the total yearly costs by 3,082.650,90 HRK. When compared to radiotherapy, immunoradiotherapy prolongs the control of the illness (14,9 vs. 24,4 months), and the overall survival of patients (29,3 vs. 49,0 months). The cost for one added life-year per patient, would be approximately 89.738,00 HRK. **CONCLUSIONS:** The inclusion of immunotherapy into the standard treatment of patients with advanced head and neck cancer would have a negative impact on the budget of the HZZO. The average costs for one added life-year are lower than the average costs of chronic kidney insufficiency patients.

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USING WHOLE DISEASE MODELLING TO INFORM ECONOMIC RECOMMENDATIONS FOR THE DETECTION, DIAGNOSIS, TREATMENT AND FOLLOW-UP OF COLORECTAL CANCER

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OBJECTIVES: Conventional economic evaluation typically involves piecemeal comparisons of competing technologies at a single isolated point in a broader care pathway. This study assesses the value of simulating whole disease and treatment pathways to provide a common economic basis for informing resource allocation decisions across an entire disease service. This "Whole Disease Modelling" approach was applied to the evaluation of technologies for the detection, diagnosis, treatment and follow-up of colorectal cancer. **METHODS:** A patient-level simulation model was developed with the intention of informing NICE's colorectal cancer clinical guideline. The model simulates disease and treatment pathways from pre-clinical disease through to detection, diagnosis, adjuvant treatment, follow-up, treatments for metastases and supportive care. The model was populated using randomised trials, observational studies, health utility studies, costing sources and expert opinion. Unobservable natural history parameters were calibrated against